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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/970,558 | 10/04/2001 | David Carver | NPB-100D5 | 8233 |

23557 7590 08/22/2003

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GAINESVILLE, FL 326066669

EXAMINER

JONES, DWAYNE C

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 08/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.



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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/535,458 | 03/24/2000 | Ronald L. Ream | P00,0369 | 2391 |

29156 7590 08/14/2003
BELL, BOYD & LLOYD LLC
P. O. BOX 1135
CHICAGO, IL 60690-1135

EXAMINER

SHARAREH, SHAHNAM J

ART UNIT PAPER NUMBER

1617

DATE MAILED 08/14/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Restart action sent to
wrong firm,
B. Shoy
8/22/03

Office Action Summary

Application No.

09/970,558

Applicant(s)

CARVER ET AL.

Examiner

Dwayne C Jones

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on the restriction response of 26 MAR 03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-369 is/are pending in the application.
- 4a) Of the above claim(s) 161-208, 257-304 and 362-369 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-160, 209-256 and 305-361 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 161-208, 257-304 and 362-369 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,4,7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-160, 209-256, and 305-361 are pending.
2. Claims 1-160, 209-256, and 305-361 are elected and rejected.
3. Claims 161-208, 257-304, and 362-369 are non-elected and withdrawn from consideration.

Election/Restrictions

4. Applicant's election without traverse of Group I, corresponding to claims -160, 209-256, and 305-361, in Paper No. 9 is acknowledged.

Information Disclosure Statement

5. The information disclosure statements filed on January 8, 2002, February 27, 2002, and January 7, 2003 have been reviewed and considered, see enclosed copies of PTO FORMs 1449.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-160, 209-256, and 305-361 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richheimer et al. in view of September 1983 National Cancer Institute Report for Taxol NSC 125973. Richheimer et al. teach that the stability of Taxol is maintained by the addition of an acid, such as acetic acid, (see page 2325 of Richheimer et al., which is also listed in Professor's Blechert's Israeli Declaration filed in the Israel Opposition to related application. In the September 1983 National Cancer Institute Report for Taxol NSC 125973, it is noted that Taxol is combined with a polyethoxylated castor oil, such as with Cremophor EL®, (see page 2). It is well known

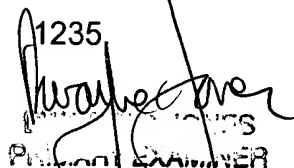
Art Unit: 1614

in the art that taxol possesses a low solubility in water. Accordingly, it would have been obvious to the ordinary artisan to combine pharmaceutically acceptable additives, excipients, and diluents in order to increase the stability of the well-known, poorly soluble anticancer agent of taxol, especially in view of the prior art references of Richheimer et al. and the September 1983 National Cancer Institute Report for Taxol NSC 125973. One having ordinary skill in the art would have been motivated to combine pharmaceutically acceptable additives, excipients, and diluents in order to increase the stability of the well-known, poorly soluble anticancer agent of taxol in view of these prior art teachings.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1235

D. C. JONES
Patent Examiner

Tech. Ctr. 1614
August 9, 2003